AMENDMENT TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Original) A solid oral controlled release pharmaceutical composition for administration to a subject in need thereof comprising:

(a) a therapeutically effective amount of a pharmaceutically active ingredient; and

(b) a controlled release modifying complex

wherein said complex comprises:

(i) a primary release modifying agent;

(ii) a secondary release modifying agent; and

(iii) an auxiliary release modifying agent

wherein said primary, secondary and auxiliary release modifying agents are present in amounts that synergistically extend the release of the pharmaceutically active ingredient.

2. (Cancelled)

3. (Original) A solid oral controlled release pharmaceutical composition for administration to a subject in need thereof comprising:

(a) a therapeutically effective amount of a pharmaceutically active ingredient; and

(b) a controlled release modifying complex

wherein said complex comprises:

(i) a primary release modifying agent selected from low molecular weight hydrophilic polymers;

(ii) a secondary release modifying agent selected from high molecular weight

hydrophilic polymers; and

(iii) an auxiliary release modifying agent selected from the starch derivatives

wherein said primary, secondary and auxiliary release modifying agents are present in amounts that synergistically extend the release of the pharmaceutically active ingredient.

4. (Original) A solid oral controlled release pharmaceutical composition for administration to a subject in need thereof comprising:

(a) a therapeutically effective amount of a pharmaceutically active ingredient; and

(b) a controlled release modifying complex

wherein said complex comprises:

(i) a primary release modifying agent selected from low molecular weight hydrophilic polymers; or

(ii) a secondary release modifying agent selected from high molecular weight hydrophilic polymers; and

(iii) an auxiliary release modifying agent selected from the starch derivatives

wherein said primary, secondary and auxiliary release modifying agents are present in amounts that synergistically extend the release of the pharmaceutically active ingredient.

5. (Original) The pharmaceutical composition of claim 1 wherein the dosage form is a tablet, caplet or capsule.

6. (Original) The pharmaceutical composition of claim 1, wherein the active pharmaceutical ingredient is a macrolide or azide antibiotic or a derivative thereof.

7. (Original) The pharmaceutical composition of claim 6, wherein the macrolide is an erythromycin derivative or its pharmaceutically acceptable hydrates, salts or esters.

8. (Original) The pharmaceutical composition of claim 6, wherein the azide is azithromycin, or its pharmaceutically acceptable hydrates, salts or esters.

9. (Original) The pharmaceutical composition of claim 7, wherein the erythromycin derivative is selected from the group consisting of clarithromycin, josamycin, midecamycin, kitamycin, roxithromycin, rokitamycin, oleandomycin, miocamycin, flurithromycin, and rosaramicin, and their pharmaceutically acceptable hydrates, salts and esters.

10. (Original) The pharmaceutical composition of claim 1, wherein the active pharmaceutical ingredient is a penicillin antibiotic or a derivative thereof.

11. (Original) The pharmaceutical composition of claim 10, wherein the penicillin derivative is selected from the group consisting of Amoxicillin, Ampicillin, Ampicillin Sodium, Apalcillin, Aspoxicillin, Azlocillin, Aztreonam, Bacampicillin, Cabenicillin, Carfecillin, Carindacillin, Ciclacillin, Cloxacillin, Dicloxacillin, and their pharmaceutically acceptable hydrates, salts and esters.

12. (Original) The pharmaceutical composition of claim 1, wherein the active pharmaceutical ingredient is a cephalosporin antibiotic or a derivative thereof.\

13. (Original) The pharmaceutical composition of claim 12, wherein the cephalosporin derivative is selected from the group consisting of Cefacetrile, Cefadroxil, Cefaloridine, Cefalothin Sodium, Cefapirin, Cefazaflur, Cefazedone, Cefazolin, Cefradine, Ceftezole, Cefsulodin Sodium, Cefamandole, Cefonicid, Cefoperazone, Cefuroxime, Cefuzonam, Cefbuperazone, Cefoxitin, Cefminox, Cefmetazole, Cefotetan, Loracarbef, Cefmenoxime, Cefodizime Sodium, Cefotaxime, Cefpimizole, Cefpiramide, Ceftazidime, Ceftiolene, Ceftizoxime, Ceftriaxone, Cefepime, Cefetecol, Cefpirome, Cefquinome,

Cefalosporin C, Cefozopran Hydrochloride, Cefaclor, Cefadroxil, Cefalexin, Cefaloglycine, Cefatrizine, Cefdinir, Cefetamet Pivoxil, Cefixime, Ceforanide, Cefotiam, Cefpodoxime, Cefpodoxime Proxetil, Cefprozil, Cefradine, Cefroxadine, Cefteram Pivoxil, Ceftibuten, Cefuroxime Axetil, and their pharmaceutically acceptable hydrates, salts and esters.

14. (Original) The pharmaceutical composition of claim 1, wherein the active pharmaceutical ingredient is a quinolone antibiotic or a derivative thereof.

15. (Original) The pharmaceutical composition of claim 14, wherein the quinolone derivative is selected from the group consisting of Nalidixic Acid, Cinoxacin, Oxolinic Acid, Flumequine, Pipemidic Acid, Rosoxacin, Norfloxacin, Lomefloxacin, Ofloxacin, Enrofloxacin, Ciprofloxacin, Enoxacin, Amifloxacin, Fleroxacin, Gatifloxacin, Gemifloxacin, Pefloxacin, Rufloxacin, Sparfloxacin, Temafloxacin, Tosufloxacin, Grepafloxacin, Levofloxacin, Moxifloxacin, Trovafloxacin, and their pharmaceutically acceptable hydrates, salts and esters.

16. (Original) The pharmaceutical composition of claim 1, wherein the active pharmaceutical ingredient is a high soluble high dose API or a derivative thereof.

17. (Currently Amended) The pharmaceutical composition of claim 16, wherein the high soluble high dose API or a derivative is selected from the group consisting of Acebutolol hydrochloride, Amantadine hydrochloride, Aminocaproic acid, Aminophylline, Amodiaquine hydrochloride, Ascorbic acid, Bupropion hydrochloride, Carbenoxolone sodium, Cefuroxime sodium, Chloroquine phosphate, Chloroquine sulphate, Chlorpromazine hydrochloride, Ciprofloxacin hydrochloride, Cloxacillin sodium, Cycloserine, Diltiazem hydrochloride, Diethyl carbamazine citrate, Doxycycline hydrochloride, Ethosuximide, Ferrous gluconate, Isoniazid, Levamisole hydrochloride,Levetiracetam, Lincomycin

hydrochloride, Mebeverine hydrochloride, Mepyramine maleate, Metformin hydrochloride, Metoprolol tartrate, Metoprolol succinate, Niacin, Nicotinamide, Nicotinic acid, Oxprenolol hydrochloride, Oxytetracycline hydrochloride, Penicillamine, Pentobarbitone sodium, Phenoxy Methyl Penicillin K, Phenytoin sodium, Piperazine adipate, Potassium chloride, Procainamide hydrochloride, Propranolol hydrochloride, Pseudoephedrine hydrochloride, Quinalbarbitone sodium, Quinine bisulphate, Ranitidine hydrochloride, Sodium amino salicylate, Sodium fusidate, sodium valproate, Streptomycin sulphate, Tetracycline hydrochloride, Topiramate, Troxidone, Verapamil hydrochloride ~~and the like~~ and their pharmaceutically acceptable salts, ester and hydrates.

18. (Original) The pharmaceutical composition of claim 17, wherein the active ingredient is Nicotinic acid.

19. (Original) The pharmaceutical composition of claim 1, wherein the active pharmaceutical ingredient is a high soluble low dose API or a derivative thereof.

20. (Currently Amended) The pharmaceutical composition of claim 19, wherein the high soluble low dose API or a derivative is selected from the group consisting of Amitriptylline hydrochloride, captopril, Clonidine hydrochloride, Colchicin, Cyclophosphamide, Diphenhydramine hydrochloride, Dothiepen hydrochloride, Doxepin hydrochloride Ephedrine hydrochloride, Ergometrine maleate, Ergometrine tartrate, Fenfluramine hydrochloride, Folic acid, Glyceryl trinitrate, Hyoscine hydrobromide, Hyoscine buytlbromide, Imipramine hydrochloride, Isoprenaline sulphate, Isosorbide dinitrate, Isosorbide-5-mononitrate, Levocetrizine hydrochloride, Methadone hydrochloride, Methdilazine hydrochloride, Metoclopramide hydrochloride, Neostigmine bromide, Oxybutynin hydrochloride, Perindopril erbumine, Pethidine hydrochloride, Phenformin hydrochloride, Pheniramine maleate, Phenobarbitone sodium, Primaquine phosphate,

Promethazine hydrochloride, Propantheline bromide, Propranolol hydrochloride, Pyridoxine hydrochloride, Salbutamol sulphate, Terbutaline sulphate, Thiamine hydrochloride, Timolol maleate, Tizanidine hydrochloride, Trifluoperazine hydrochloride, Triflupromazine hydrochloride, Triprolidine hydrochloride, Warfarin sodium ~~and the like~~ and their pharmaceutically acceptable salts, ester and hydrates.

21. (Original) The pharmaceutical composition of claim 20, wherein the active ingredient is Oxybutynin hydrochloride.

22. (Original) The pharmaceutical composition of claim 1, wherein the active pharmaceutical ingredient is a low soluble high dose API or a derivative thereof.

23. (Currently Amended) The pharmaceutical composition of claim 22, wherein the low soluble high dose API or a derivative is selected from the group consisting of Acetazolamide, Allopurinol, Atenolol, Carbamazepine, Cefadroxil, Cephalexin, Chloramphenicol, Cefuroxime Axetil, Chlorthalidone, Cilastozol, Cimetidine, Clarithromycin, Clofazemine, Dapsone, Diclofenac sodium, Diiodohydroxy quinolone, Diloxanide furoate, Disulfiram, Erythromycin, Erythromycin estolate, Erythromycin stearate, Ethacrynic cid, Ethionamide,, Ethopropazine hydrochloride, Ferrous fumarate, Fluconazole, Flurbiprofen, Furazolidone, Griseofulvin, Hydrochlorthiazide, Ibuprofen, Itraconazole, Ketoconazole, Ketoprofen, Labetalol hydrochloride, Levodopa, Linezolid, Lithium carbonate, Magaldrate, Mebendazole, Mefenamic acid, Megestrol acetate, Mercaptopurine, Mesalamimne, Nalidixic acid, Nateglinide, Niclosamide, Nitrofurantoin, Norfloxacin, Oxcarbazepine, Oxyphenbutazone, Paracetamol, Phenindione, Phenobarbitone, Phenylbutazone, Phenylsulphathiazole, Piperazine phosphate, Proguanil hydrochloride, Promethazine theoclate, Propylthiouracil, Quinidine sulphate, Quinine sulphate, Quinidochlor, Rifampicin, Simvastatin, Spironolactone, Succinylsulphathiazole,

Sulphadiazine, Sulphadimethoxine, Sulphadimidine, Sulphafurazole, Sulphaphenazole, Thiabendazole, Tinidazole, Tolbutamide, Triamterene, Sulphamethoxazole ~~and the like~~ and their pharmaceutically acceptable salts, ester and hydrates.

24. (Original) The pharmaceutical composition of claim 23, wherein the active ingredient is Clarithromycin.

25. (Original) The pharmaceutical composition of claim 1, wherein the active pharmaceutical ingredient is a low soluble low dose API or a derivative thereof.

26. (Currently Amended) The pharmaceutical composition of claim 25, wherein the low soluble low dose API or a derivative is selected from the group consisting of Alprazolam, Amiloride hydrochloride, Astemizole, Atorvastatin, Benzhexol hydrochloride, Betamethasone, Bromhexine hydrochloride, Bromocryptine mesylate, Buprenorphine hydrochloride, carbimazole, Chlordiazepoxide, Citalopram, Cortisone acetate, cyproheptadine hydrochloride, diazepam, Desloratadine, Dexamethasone hydrochloride, Dextromethorphan hydrochloride, dicyclomine hydrochloride, Dienoestrol, Digitoxin, Digoxin, Domperidone, Dydrogesterone, enalapril maleate, Esomeprazole, Ethinyloestradiol, Ethyloestrenol, Fludrocortisone acetate, Frusemide, glibenclamide, Glimepiride, haloperidol, Indomethacin, Isoxsuprine hydrochloride, Lanatoside C, Lercanidipine hydrochloride, Levonorgesrtel, Lomustine, Loratadine, Isoxuprine hydrochloride, methotrexate, Mecizine hydrochloride, Melphalan, Methotrexate, Methylergometrine maleate, Methylprednisolone, Mianserin hydrochloride, Mosapride, Nicoumalone, Nifedipine, Nitrazepam, Norethisterone, nortriptyline hydrochloride, Omeprazole, Ormeloxifene hydrochloride, Pentazocine hydrochloride, Phenindamine tartrate, piroxicam, prazosin hydrochloride, Prednisolone, Prednisone, Prochlorperazine maleate, Repaglinide, Riboflavinee, Rosuvastatin, Stilbostrol,

Tamoxifen citrate, Thyroxine sodium, triamcinilone, Trimethoprim, Valdecoxib, Zolpidem tartrate ~~and the like~~ and their pharmaceutically acceptable salts, ester and hydrates.

27. (Original) The pharmaceutical composition of claim 26, wherein the active ingredient is Alprazolam.

28. (Original) The pharmaceutical composition of claim 26, wherein the active ingredient is Lercanidipine hydrochloride.

29. (Original) The pharmaceutical composition of claim 1, wherein the primary release modifying agent is a low molecular weight polyethylene oxide.

30. (Original) The pharmaceutical composition of claim 1, wherein the low molecular weight polyethylene oxide has a molecular weight of at least about 100,000.

31. (Original) The pharmaceutical composition of claim 1 wherein the low molecular weight polyethylene oxide has a molecular weight ranging from 100,000 to 900,000.

32. (Original) The pharmaceutical composition of claim 1, wherein the secondary release modifying agent is a high molecular weight polyethylene oxide.

33. (Original) The pharmaceutical composition of claim 1, wherein the high molecular weight polyethylene oxide has a molecular weight of at least about 1,000,000.

34. (Original) The pharmaceutical composition of claim 1, wherein the high molecular weight polyethylene oxide has a molecular weight ranging from 1,000,000 to 9,000,000.

35. (Original) The pharmaceutical composition of claim 1, wherein the auxiliary release modifying agent is a starch derivative selected from pregelatinized starch, partially pregelatinized starch, retrograded starch, or a combination thereof.

36. (Original) The pharmaceutical composition of claim 1, wherein the auxiliary release modifying agent is a retrograded starch.

37. (Original) The pharmaceutical composition of claim 1, wherein said composition further comprises at least one pharmaceutically acceptable additive selected from diluents, fillers, binders, glidants, and lubricants.

38. (Original) The pharmaceutical composition of claim 1, wherein said composition further comprises an optional coating which is designed for the modification of drug release.

39. (Currently Amended) The pharmaceutical composition of claim 38, wherein the coating composition is selected from the group consisting of cellulose ethers, ~~such as ethyl cellulose, hydroxypropyl methyl cellulose, hydroxypropyl cellulose, others such as~~ polyvinyl alcohol, polyvinyl pyrrolidone, methacrylic acid derivatives, resins, clays, long chain hydrocarbons, long chain carboxylic acids, long chain carboxylic acid esters, long chain alcohols ~~and the like~~ and mixtures thereof.

40. (Original) The pharmaceutical composition of claim 1, wherein said composition further comprises an optional coating which is not designed for the modification of drug release.

41. (Currently Amended) The pharmaceutical composition of claim 40, wherein the coating composition is selected from the group consisting of cellulose ethers, ~~such as ethyl cellulose, hydroxypropyl methyl cellulose, hydroxypropyl cellulose, others such as~~ polyvinyl alcohol, polyvinyl pyrrolidone, methacrylic acid derivatives, resins, clays, long chain hydrocarbons, long chain carboxylic acids, long chain carboxylic acid esters, long chain alcohols ~~and the like~~ and mixtures thereof.

42. (Original) The pharmaceutical composition of claim 1, wherein said composition comprises from about 0.1 percent weight to about 90 percent weight of the active pharmaceutical ingredient.

43. (Original) The pharmaceutical composition of claim 42, wherein said composition comprises from about 0.1 percent weight to about 80 percent weight of the active pharmaceutical ingredient.

44. (Original) The pharmaceutical composition of claim 1, wherein the composition comprises from about 1 percent weight to about 90 percent weight of the release modifying complex.

45. (Original) The pharmaceutical composition of claim 44, wherein the composition comprises from about 5 percent weight to about 85 percent weight of the release modifying complex.

46. (Original) The pharmaceutical composition of claim 45, wherein the composition comprises from about 10 percent weight to about 80 percent weight of the release modifying complex.

47. (Original) The pharmaceutical composition of claim 1, wherein the primary release modifying agent comprises from about 1 percent weight to about 90 percent weight of the release modifying complex.

48. (Original) The pharmaceutical composition of claim 47, wherein the primary release modifying agent comprises from about 5 percent weight to about 80 percent weight of the release modifying complex.

49. (Original) The pharmaceutical composition of claim 48, wherein the primary release modifying agent comprises from about 5 percent weight to about 70 percent weight of the release modifying complex.

50. (Original) The pharmaceutical composition of claim 1, wherein the secondary release modifying agent comprises from about 1 percent weight to about 95 percent weight of the release modifying complex.

51. (Original) The pharmaceutical composition of claim 50, wherein the secondary release modifying agent comprises from about 5 percent weight to about 90 percent weight of the release modifying complex.

52. (Original) The pharmaceutical composition of claim 1, wherein the auxiliary release modifying agent comprises from about 1 percent weight to about 95 percent weight of the release modifying complex.

53. (Original) The pharmaceutical composition of claim 52, wherein the auxiliary release modifying agent comprises from about 5 percent weight to about 95 percent weight of the release modifying complex.

54. The pharmaceutical composition of claim 53, wherein the auxiliary release modifying agent comprises from about 10 percent weight to about 95 percent weight of the release modifying complex.

55-145. (Cancelled)